

Exhibit B



Deposition of:
Rebecca Betensky , Ph.D.

June 23, 2017

In the Matter of:
**In Re: Bard IVC Filters Products
Liability**

Veritext Legal Solutions

1075 Peachtree St. NE , Suite 3625

Atlanta, GA, 30309

800.808.4958 | calendar-atl@veritext.com | 770.343.9696

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1 for newer devices on the market as opposed to older
2 devices, right?

3 MR. MANKOFF: Object to form.

4 A Again, my understanding is that this is a
5 sys -- it's a complex system and that is -- one driver
6 of reporting is the newness of the device, but there
7 are other -- may be other drivers as well.

8 Q Let me see if I can restate that.

9 One driver of reporting that you understand
10 exists for medical devices in a general sense is that
11 newer medical devices are likely to receive more
12 reports as recorded in MAUDE than older devices, right?

13 A I don't know about likely. I can't say are
14 likely to. I can say that's a possibility.

15 Q Let me try it again.

16 You recognize that it's possible that newer
17 devices have more MAUDE reports of adverse events than
18 older devices, right?

19 A That's possible.

20 Q In your analysis you captured periods in
21 which the removal devices were new to the market,
22 right?

23 A Yes.

24 Q In your analysis you didn't start considering
25 adverse events for the Simon Nitinol filter until it

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1 had been on the market for over ten years, right?

2 A I believe that's true.

3 Q *You did not do an apples-to-apples
4 comparison of time periods for any of the removable
5 filters as compared to the analogous time periods in
6 which the Simon Nitinol filter had been on the market,
7 right?

8 MR. ROTMAN: Please reread that
9 question.

10 (*Record read)

11 MR. MANKOFF: Object to form.

12 THE WITNESS: I'm sorry. Can you
13 restate that, please.

14 MR. BUSMAN: Sure.

15 Q If you really wanted to do an accurate and
16 meaningful comparison between various of the Recovery
17 filters and the Simon Nitinol filter, you would have
18 wanted to compare MAUDE reports for any of the
19 recoverable filters in the first few years those
20 filters had been on the market as compared to the
21 reports for the first few years when the Simon Nitinol
22 filter was on the market, right?

23 MR. MANKOFF: Object to form.

24 A Well, that's one analysis certainly, but I
25 guess I'm -- or let me back up. But another way of

1 the typo but ...

2 Q I think we're, I think we're -- I think maybe
3 I'm, I'm asking a different question, okay?

4 If you take a look at your rebuttal to
5 Dr. Feigal's report, paragraph 5, the response.

6 A Yes.

7 Q In the response, one, two, three lines you
8 state, "In my report, I used the term "risk" to mean
9 proportion, and I distinguish this from a rate, which I
10 agree cannot be calculated (see my section on Potential
11 limitations and responses, No person-time exposure/
12 cannot calculate incidence rates and ratios)." Did I
13 read that correctly?

14 A You did. And I was making the point that --
15 a nuanced point, as I said, that I cannot calculate the
16 rate. That is true and it remains true. But I can, I
17 believe, bound that rate in reference to the reporting
18 risk ratio.

19 Q I understand. But for purposes of your
20 expert opinions in this case, whether you can or you
21 cannot, you did not calculate a rate, true?

22 A That is true.

23 Q Okay. So let me try it again.

24 You did not calculate any rate in connection
25 with your expert opinions in this case, right?

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1 A I did not calculate any rate. I calculated
2 what I call risk or proportion.

3 Q If somebody cites your report or your
4 deposition and asserts that you have in any way
5 calculated a rate of adverse events for any filter,
6 that would be incorrect, right?

7 A No, I would -- I wouldn't go so far as to say
8 it would be incorrect. I would say that perhaps that
9 person doesn't have exactly the nuanced understanding
10 or is -- or maybe they have an understanding, but
11 they're not making the nuanced technical distinction
12 that I am making between a rate and a risk.

13 Even Dr. Thisted who's a very, very prominent
14 statistician -- I'll take that back. He knows the
15 difference between a rate and risk although -- so let
16 me take that back.

17 Many people confuse the notion of rate and
18 risk. I'm writing a paper right now with a neurologist
19 who is making that -- you know, who's confusing those
20 concepts. So it's possible somebody is referring to my
21 report and carelessly calling it a rate when I'm using
22 the risk, and they mean risk.

23 Q I understand. That was helpful. Let me do
24 what I've done before and try to drill down.

25 A Okay.

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1 scientific background; did I understand you to testify
2 to that?

3 A What I'm saying is that people -- some people
4 might not make the distinct -- the careful distinction
5 that a statistician would likely make between a risk
6 and a rate. People may use different language as well.

7 Q You would agree that at a minimum a
8 statistician would have an appropriate understanding of
9 the difference between a risk and a rate, a
10 statistician, right?

11 A A statistician would understand. It's not to
12 say that in writing something they might not be -- it's
13 possible that they might not be careful. And you know,
14 you probably if you went -- let me finish that
15 sentence. They might not be careful in making the
16 distinction. And if you went through my CV maybe you
17 would even find papers that I wrote. So it depends on
18 the context.

19 Q If someone described your report and stated
20 that you had calculated any rates, that would not be a
21 careful distinction between risk and rate, right?

22 A That would not be what I had done in my
23 report.

24 Q Now, still on ... where is it? Dr. Feigal's
25 report. Excuse me, still on the rebuttal to